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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,506	06/13/2001	Donald K. Jones	CRD0935	5338
27717	7590	12/13/2004	EXAMINER	
SEYFARTH SHAW 55 EAST MONROE STREET SUITE 4200 CHICAGO, IL 60603-5803			ODLAND, KATHRYN P	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/880,506	Applicant(s) JONES ET AL. en	
	Examiner Kathryn Odland	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-14, 16, 17, 20 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-14, 16, 17, 20 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment/RCE

This is a response to the Amendment/RCE dated August 23, 2004. Claims 1-4, 6-14, 16, 17, 20 and 27 are under consideration.

Response to Remarks

Applicant has amended claims 1, 11 and 20 to include the limitation: "having a relatively smooth surface as compared to the surface of the distal portion and the distal portion having a relatively textured surface as compared to the smooth surface proximal portion." The prior limitation, "being relatively smooth and the distal portion having a relatively textured surface" has been removed. This prior limitation in stating "relatively smooth" and "relatively textured" is relative. In order to properly understand the scope of the limitation, the examiner went to the specification to establish the basis for what would be "relatively smooth" and "relatively textured." The amendments change the scope of the claim and a new rejection has been applied.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 11 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Engelson in US Patent No. 5,261,916.

Regarding claims 1, 11 and 20, Engelson discloses a method for occluding the vasculature/treating an aneurysm of a patient. There is an introducer (generally @ 11 and associated components) having a detachment portion (such as 20) for holding and releasing an embolic coil (13). The method of use involves providing a plurality of embolic coils (generally at 13) having a proximal portion that is held by the detachment portion (20), as seen in figures 1-3. The proximal portion would have a relatively smooth surface as compared to the surface of the distal portion and the distal portion would have a relatively textured portion as compared to the smooth surface of the proximal portion. The proximal portion/end is a round ball that is smooth. The distal portion of the coil is spirally wound, thus a texture is imparted. If you were to run your finger over the ball and then the coil – you would feel the texture imparted by the helix configuration. The coils are introduced using the introducer and the texturing provides improved platelet adhesion compared to a non-textured surface to promote clotting. If the wire were not wound helically, it would be smooth and would not promote as much clotting.

3. Claims 4 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Engelson in US Patent No. 5,261,916.

Regarding claims 4 and 14, Engelson discloses that as applied to claims 1 and 11, as well as a coil that is of a metal such as platinum or tungsten. Thus, it

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would be obvious if not inherent to have the coil be a tungsten-platinum alloy, for they are extremely well known in the art.

4. Claims 1, 11 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by McGurk et al. in US Patent No. 5,690,671.

Regarding claims 1, 11 and 20, McGurk et al. disclose a method for occluding the vasculature/treating an aneurysm of a patient. McGurk et al. incorporate by reference US Patent No. 5,261,916 and recite in column 5, lines 30-35, "In some cases, it may be necessary to adapt or modify the construction of the embolic element to be compatible with the known delivery systems, for example, by including an anchor or a latch member at either or both ends of the embolic element to facilitate delivery." Thus, as shown in US Patent No. 5,261,916 there is an introducer (generally @ 11 and associated components) having a detachment portion (such as 20) for holding and releasing an embolic coil. McGurk et al. disclose a coil (12), which would be modified to be used in the deployment system of US Patent No. 5,261,916. McGurk et al. for use in the deployment system of US Patent No. 5,261,916 would provide a plurality of embolic coils (generally at 12) having a proximal portion that is held by the detachment portion, as seen in figures 1-3 of US Patent No. 5,261,916. The proximal portion would have a relatively smooth surface as compared to the surface of the distal portion and the distal portion would have a relatively textured portion as compared to the smooth surface of the proximal portion. McGurk et al.

disclose texturing the coils in column 5, lines 5-20. As incorporated in reference, the deployment system of US Patent No. 5,261,916 shows a smooth round ball and states it may be attached as a separate segment to the coil, in column 3, lines 5-12. Therefore, the proximal segment would necessarily be smooth as compared to the distal portion that is textured. Moreover, McGurk et al. also disclose introducing the plurality of embolic coils into the patient's vasculature/aneurysm using the introducer that is coupled to the proximal portion, whereby the textured surface provides improved platelet adhesion compared to a non-textured surface to promote clotting, as discussed throughout the specification and seen in the figures and that of US Patent No. 5,261,916.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2, 3, 6-10, 12, 13, 16, 17, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGurk et al. in US Patent No. 5,690,671.

Regarding claims 2, 3, 12 and 13, McGurk et al. disclose the system as applied to claims 1 and 11. However, McGurk et al. do not recite texturing the surface of an embolic coil by abrasion or sandblasting. On the other hand, McGurk et al. clearly disclose surface texturing in column 5, lines 5-20. Abrasion

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and sandblasting are well known texturing techniques that would be obvious to one with ordinary skill in the art and within the scope of the invention.

Regarding claims 6 and 16, McGurk et al. disclose that as applied to claims 1 and 11. However, McGurk et al. do not recite a coil that has a substantially uniform roughness having pockets having diameters between about 0.125 microns and about 50 microns. On the other hand, McGurk et al. clearly disclose surface texturing in column 5, lines 5-20. Abrasion and sandblasting are well known texturing techniques that would be obvious to one with ordinary skill in the art and within the scope of the invention. Thus, when texturing via the known methods of abrasion and sandblasting a coil that has a substantially uniform roughness having pockets having diameters between about 0.125 microns and about 50 microns is within the scope. Further, the current specification does not demonstrate the criticality of an embolic coil that has substantially uniform roughness with pockets having diameters between about 0.125 microns and about 50 microns. In fact, page 5 of the specification recites, "***Although no limitation is intended***, as a specific example the texturization provides a uniform roughness comprising pockets having diameters between about 0.125 microns and about 50 microns and depths between about 0.25 microns and about 20 microns."

Regarding claims 7, 17 and 27, McGurk et al. as modified discloses that as applied to claim 6 and discloses that as applied to claims 11 and 20. Further, although not explicitly recited, an embolic coil that has pockets that have depths of between about 0.25 microns and about 20 microns would be obvious to one with ordinary skill in the art and within the scope of the invention. Further, the current specification does not demonstrate the criticality of an embolic coil that has pockets that have depths of between about 0.25 microns and about 20 microns. In fact, page 5 of the specification recites, "***Although no limitation is intended***, as a specific example the texturization provides a uniform roughness comprising pockets having diameters between about 0.125 microns and about 50 microns and depths between about 0.25 microns and about 20 microns." Thus, when modifying the invention of Wallace et al. to include texturing for the purpose of promoting clotting, it would be obvious to assure that the embolic coil that has pockets that have depths of between about 0.25 microns and about 20 microns as within the scope of the invention although not explicitly recited. Abrasion and sandblasting are well known texturing techniques that would be obvious to one with ordinary skill in the art and within the scope of the invention. Thus, when texturing via the known methods of abrasion and sandblasting a coil would necessarily fall within the range of texturing as claimed.

Regarding claims 8-10, Wallace et al. disclose the system as applied to claim 1 above. Claim 8 recites, "the embolic coils are used to embolize a vessel

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for vessel sacrifice." Claim 9 recites, "the embolic coils are used to reduce or block blood flow to an arterial-venous malformation or to a fistula." Claim 10 recites, "the embolic coils are used to block blood flow to tumor." These claims are alternates of intended use and within the scope of the invention although not explicitly recited. Furthermore, the criticality for these intended use limitations have not been demonstrated in the specification of the current application. The intended use would be inherent in the treatment and within the scope of the invention.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure is US Patent No. 5,382,259. This document also shows a smooth tip (124) and a braided portion over the coil, which imparts texturing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (571) 272-4801. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



Henry Bennett
Supervisory Patent Examiner
Group 3700